Press Release

BSE: 500257 NSE: LUPIN REUTERS: LUPIN.BO BLOOMBERG: LPC IN

Lupin submits Marketing Authorization Application for Etanercept Biosimilar in Europe

Mumbai, May 25, 2018: Pharma major Lupin announced today that its Marketing Authorization Application (MAA) for a biosimilar of Etanercept has been accepted for review by the European Medicines Agency (EMA). The indications targeted for approval are Rheumatoid Arthritis (RA), Psoriatic Arthritis, Ankylosing Spondylitis, Axial spondyloarthritis, Non-radiographic axial spondyloarthritis and Plaque Psoriasis. This follows an application that was made to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) in March this year.

"The application for our Etanercept biosimilar and its acceptance in Europe is a significant milestone for our foray into biosimilars in key developed markets. This is also an encouraging development as we continue building our pipeline of higher complexity products," said **Mr. Nilesh Gupta, Managing Director** of Lupin Limited.

Earlier this month, Lupin announced the filing of the NDA in Japan through YL Biologics (YLB), the joint venture of Lupin Limited and Yoshindo along with an additional filing from Kyowa, Lupin's Subsidiary in Japan. YL Biologics had also announced the successful conclusion of its global Phase III study of biosimilar of Etanercept (YLB113) in February 2018. The first-of-its-kind study was a multinational randomized double-blind controlled trial of 52 weeks duration, which included more than 500 patients with rheumatoid arthritis (RA) in 11 countries. It compared YLB113's efficacy and safety directly against Enbrel® (of Amgen/Pfizer). The study was conducted at 110 rheumatology clinics across Japan, Europe and India. This study included over 230 patients from Europe.

"Etanercept (YLB113) is the first biosimilar developed in-house by Lupin and this makes us the first Indian pharmaceutical company to file for a complex fusion protein like Etanercept in regulated markets. This is a significant step in the fight against severe auto-immune disorders that calls for an effective, affordable equivalent for patients across Europe. Lupin has made significant investments in the biosimilars space over the last decade, and this application is an important achievement for us in our journey for future developments in biologics." said **Dr. Cyrus Karkaria, President - Biotechnology** at Lupin.

This filing also opens up other key markets like Canada, Australia, the Middle East, South East Asia and Latin America. The approvals for these markets are expected within the next 12 to 18 months. The ex-US market for Etanercept is estimated at USD 4 billion in Japan and Europe, along with other regulated and emerging markets. Lupin is on course with its plans for biosimilar Etanercept filing in the US and is targeting the same in FY 2019-20.

About Etanercept

Enbrel® (Etanercept) was the first TNF biologic treatment to be FDA approved for moderate to severe RA in 1998, and is used in the treatment of five long-term inflammatory conditions. These are moderate to severe rheumatoid arthritis, moderate to severe plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and moderate to severe polyarticular juvenile idiopathic arthritis (JIA).

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About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 12th and 8th largest generics pharmaceutical company by market capitalization (March 31, 2018, Bloomberg) and revenues (December 30, 2017, Bloomberg LTM) respectively. The Company is the 4th largest pharmaceutical player in the US by prescriptions (IQVIA MAT March 2018); 3rd largest Indian pharmaceutical company by global revenues (December 30, 2017 Bloomberg LTM); 6th largest generic pharmaceutical player in Japan and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT March 2018).

For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits were at Rs. 155,598 million (USD 2.41 billion) and Rs. 2,513 million (USD 39 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal

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